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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SMITH, CAROLYN L	
ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/993,312	HOOD ET AL.	
	Examiner	Art Unit	
	Carolyn L. Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/12/06*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-74* is/are pending in the application.

4a) Of the above claim(s) *34 and 44-74* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-33 and 35-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments and remarks, filed 6/12/06, are acknowledged. Cancelled claim 3 is acknowledged.

Applicant's arguments, filed 6/12/06, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims herein under examination are 1-2, 4-33 and 35-43. Claims 34 and 44-74 are withdrawn as being drawn to a non-elected species and non-elected Groups.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-2, 4-33 and 35-43 are rejected under 35 U.S.C. 101 because these claims are directed to non-statutory subject matter.

This rejection is maintained.

Under the Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility (published in the O.G. notice (1300 OG 142) on 11/22/2005) a method that does not result in a physical transformation of matter MAY be statutory where it recites a concrete, tangible and useful result; i.e. a practical application.

In the instant case, the claims are directed to a method of predicting a behavior of a biochemical system via producing a comparison and identifying correlative changes. Although correlative changes are identified, these results are not presented in a tangible form. This predicting method does not result in a physical transformation of matter, nor is any concrete, tangible and useful result produced/recited. Therefore, these claims are not statutory.

Applicants summarize the rejection. Applicants' argue that the Board of Appeals and Interferences of the USPTO has now overturned rejections attempting to require method claims to include machine or computer processing limitations, such as a requirement for a physical transformation or an interaction with a computer. This statement is found unpersuasive. It is noted that the examiner has not "required" that the claims recite a physical transformation nor interaction with a computer. The previous office action stated that where the claims do not recite a physical transformation of matter, they MAY be statutory where they recite a concrete, tangible and useful result; i.e. practical application. This is in accordance with the Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility (published in the O.G. notice (1300 OG 142) on 11/22/2005) and the decision in in re Lundgren. It is further noted that applicant does not argue that the claims do, in fact, recite a physical transformation of matter nor does applicant argue that the claims recite a concrete, tangible and useful result. In the instant case, neither kind of result is present, as previously set forth and reiterated above. Therefore, the claims remain rejected as being drawn to non-statutory subject matter.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4-33 and 35-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Rine et al. (P/N 5,777,888).

This rejection is maintained.

Rine et al. disclose analyzing stimulus-response patterns of a living thing using deduction protocols applied through artificial intelligence systems such as expert systems and neural networks (abstract) which represents predicting the behavior of a biochemical system, as stated in instant claims 1, 16, and 32. Rine et al. disclose performing comparisons to deduce the mechanism of action and characteristics of the responsible stimulus (col. 5, lines 37-49) which represents a prediction of cell behavior (of a biochemical system) indicative of a changing condition, as stated in claims 1, 16, and 32. Rine et al. disclose constructing a stimulated physical matrix (data integration map which is a physical interaction map), detecting a physical signal (value) at each unit of the physical matrix and storing the data with X and Y coordinates of the corresponding physical matrix unit and stimulus, and repeating this procedure to form a database (col. 2, lines 4-15). Rine et al. disclose using various conditions/perturbations, including pharmaceutical agent stimuli, suspected pathogenic agents, and radiative energy (col.

3, lines 48-51) which represent two or more different perturbed conditions, as stated instant claims 1, 7, 16, 22, 32, and 36. The term "network" is broadly defined in several ways in the instant specification (page 10, line 26 to page 11, line 32) that includes a group of interacting molecules in two or more pathways and have common function in a biochemical function. A "network" is also defined as containing one or more components involved in a biochemical function which could be interpreted to be a cell, nucleic acid, or countless other cellular component parts. Thus, two cells involved in each microarray as discussed by Rine et al. would qualify as two independent networks, as stated in instant claims 1, 2, 16, 17, 32, and 33. Rine et al. disclose using a microtiter plate with 96 wells with a cell or colony of cells in each well (col. 10, lines 38-41) which represent at least 96 networks, as stated in instant claims 6, 21, and 35. Rine et al. disclose comparing an output signal matrix to an output signal matrix database (containing other matrices) for correlating candidate stimuli and responses (abstract and col. 1, line 66 to col. 2, line 3 and col. 2, lines 25-29) which represents identifying correlative changes predicting a behavior indicative of a changing condition, as stated in instant claims 1, 16, and 32. Rine et al. disclose performing comparisons to generate correlates and qualitative and/or quantitative deduction analyses (col. 5, lines 56-63 and Figure 5) which represents producing a comparison of two or more data integration maps and identifying correlative changes in at least two value sets, as stated in instant claims 1, 16, and 32. Rine et al. disclose using an array containing a different responder of a living thing in each unit which may comprise an organism's entire repertoire of responders including genes, gene regulatory elements, gene transcripts (mRNA) or translates (proteins), or a predetermined functional class or subset of the organism's entire repertoire as well as a sufficient ensemble of responders to deduce the action of a stimulus

(col. 2, lines 30-44) which represent at least three different types of data elements within value sets (as stated in instant claims 1, 4, 16, 18, 19) and at least five components (as stated in instant claims 14, 29, and 41). Rine et al. disclose measuring gene expression levels in cells (col. 4, lines 11-17) and using various conditions/perturbations, including pharmaceutical agent stimuli, suspected pathogenic agents, and radiative energy (col. 3, lines 48-51) which represent a nucleic acid expression data element type and a physical interaction data element, as stated in instant claims 5, 13, 15, 20, 28, 31, 32, 40, and 43. Rine et al. disclose measuring responses for each cell in the matrix under a variety of conditions, such as pH, temperature, medium, and osmolarity (col. 11, lines 21-28) which represents multiple data elements. Rine et al. disclose measuring cells of the matrix before and after interactions with a pharmacological agent which might include monitoring as a function of other variables such as stimulus intensity, duration, or time (col. 4, lines 51-57) which represents repeated measurements on at least two value sets with three data element types with perturbed conditions for substantially all components within at least one network (as stated in instant claims 8, 23, and 37) as well as obtaining a first integration map and producing a second integration map under a perturbed condition, as stated in instant claims 16 and 32. Values taken during the drug interaction measurements over time as discussed above in a 96-well microtiter plate represent value sets within the same network (measurements in the same well) as well as within different networks (measurements in different wells) as stated in claims 9, 10, 24, and 25. Rine et al. disclose a system for creating physical matrices, storing the matrices in a database, and a comparison function (col. 3, lines 9-19) as well as repeating the process of creating response profiles for compounds 2 through N (any number, i.e. 3) (col. 11, lines 30-40) which represents data integration maps comprising changes in three or more value

sets, as stated in instant claims 11, 26, and 38. Rine et al. disclose similarities in a shared response pathway in sterol biosynthesis between human cells and yeast cells resulting increased expression levels but in different nucleic acids when exposed to drug Mevacor (col. 6, lines 14-28). Rine et al. disclose using a microtiter plate to test an inhibitor on various strains of yeast which varies in no expression, increased expression, or decreased expression depending on the strains (col. 6, lines 44-54) which represents inversely coordinated changes in nucleic acid expression data elements, as stated in claims 12, 27, and 39. Rine et al. disclose measuring cells of the matrix before and after interactions (col. 4, lines 51-57) as well as constructing a stimulated physical matrix, detecting physical signals, storing the data, and iteratively storing signal matrix data for a plurality of stimuli to form a matrix database (col. 2, lines 4-15) which represents repeating steps at least once under a different perturbed condition, as stated in instant claims 30 and 42. Rine et al. disclose comparing a response profile to a reference profile and repeating the process for compounds or mixtures of compounds 2 through N (col. 11, lines 29-40). Rine et al. disclose using this procedure in testing drug administration (perturbation and physical interaction) to identify compounds with a particular biological effect (col. 1, lines 40-57). Rine et al. disclose steps to generate various response profiles (including value sets) for known and unknown stimuli (col. 2, lines 60-64). Rine et al. disclose using a wide variety of stimuli and adjusting incubation conditions to preclude cellular stress (col. 3, lines 59-63). Thus, Rine et al. anticipate the instant invention.

Applicants summarize the Rine et al. rejection. Applicants summarize the requirements for a finding of anticipation. Applicants argue that Rine et al. fail to anticipate the limitations of

two or more data integration maps having value sets containing two or more different types of data elements. This statement is found unpersuasive as this limitation is addressed several times in Rine et al., for example:

Rine et al. disclose constructing a **stimulated physical matrix (data integration map),** detecting a signal (value) at each unit and storing X and Y coordinates of a corresponding **(second) physical matrix and stimulus** (col. 2, lines 4-15) wherein two cells involved in each microarray qualify as two networks (col. 10, lines 38-41). Rine et al. also disclose comparing an output signal matrix to a matrix database (for correlating stimuli and responses (abstract and col. 1, line 66 to col. 2, line 3 and col. 2, lines 25-29) and performing comparisons to generate correlates and qualitative and/or quantitative deduction analyses (col. 5, lines 56-63 and Figure 5) which represents producing a comparison of two or more data integration maps and identifying correlative changes in at least two value sets. Furthermore, Rine et al. disclose using an array containing a different responder of a living thing in each unit which may comprise an organism's entire repertoire of responders including genes, gene regulatory elements, gene transcripts (mRNA) or translates (proteins), or a predetermined functional class or subset of the organism's entire repertoire as well as a sufficient ensemble of responders to deduce the action of a stimulus (col. 2, lines 30-44) which represent at least three different types of data elements within value sets. In addition, Rine et al. disclose measuring gene expression levels in cells (col. 4, lines 11-17) and using various conditions/perturbations, including pharmaceutical agent stimuli, suspected pathogenic agents, and radiative energy (col. 3, lines 48-51) which represent a nucleic acid expression data element type and a physical interaction data element. Rine et al. disclose measuring responses for each cell in the matrix under a variety of conditions, such as pH, temperature, medium, and osmolarity (col. 11, lines 21-28) which represents multiple data elements.

Applicants argue that Rine et al. compare values obtained from microarray profiles without integration of different types of results into a value set as claimed. Applicants argue that Rine et al. fail to describe two or more different types of data elements integrated into a value set. This statement is found unpersuasive as the instant claims do not recite an "integration of different types of results" or "data elements integrated into a value set", but rather data integration maps. It is noted the instant claims recite that the data integration maps comprise at least two networks. Rine et al. disclose physical matrices involving cells (col. 2 and 10) which represent data integration maps.

Applicants state that the application teaches that a data integration map is a set of data elements describing interactions, interrelations, and interdependencies of network constituents. It is noted that the physical matrices of Rine et al. represent such a set of data elements.

Applicants state that a value set means two or more types of data elements that characterize a component of a biochemical system. Applicants state that the claimed method compares two or more different types of data elements between two or more value sets. Applicants argue that the Office fails to cite a passage or describe where Rine et al. describe an integration map containing value sets with different types of data. This argument is addressed above.

Applicants argue that there is nothing in the Office's assertion that supports that Rine et al. describe an integration map as claimed. This statement is found unpersuasive as the passages stated above describe the data integration map. Applicants argue that a physical matrix does not describe an integration of data elements and value sets as described because a physical matrix corresponds to things whereas an integration map corresponds to data elements and values. This statement is found unpersuasive as Rine et al. describe the physical matrices and various data elements including an array containing a different responder of a living thing in each unit and an ensemble of responders to a stimulus (col. 2, lines 30-44) which represent interactions of various data elements within a set of data elements. Applicants admit that a physical interaction map can be a subset of integration maps as claimed. Applicants state that the physical interaction map can be a subset of integration maps if it contains interaction data. It is noted that stimulus data are clearly forms of interaction data, for example, between the responder and the stimulus.

Applicants argue that there is no description at col. 2, lines 4-15 (of Rine et al.) of indexed set of data elements within value sets that describe interactions of components. This statement is found unpersuasive as Rine et al. disclose output signals with X and Y coordinates corresponding to the physical matrix unit and stimulus (col. 2, lines 4-15) where there was interaction with a stimulus. Applicants argue that the Rine et al. results are related back to the responders and not to each other. It is noted that instant claims do not limit anything to "relate back" to anything else. Applicants appear to be adding limitations into the instant claims that are not present. Further, Applicants appear to be arguing a narrow interpretation of the claims that is not specifically reflected by the claimed limitations. Applicant is reminded that, absent a limiting definition in the specification, claims terms are interpreted broadly.

Applicants argue that the passage at column 5, lines 56-63 and Figure 5 of Rine et al. fail to describe a comparison of two or more data integration maps and identify correlative changes in at least two value sets. Applicant is reminded that a reference is relied upon for the totality of its teachings. Without reiterating the entire Rine et al. patent, the rejection is written in a manner such that sections are summarized throughout the rejection to point to key passages taught by Rine et al. to thereby address ALL of the limitations recited in the rejected claims. Column 5 of Rine et al. disclose a processing data structures for comparison against databases and performing comparisons to generate correlates and qualitative analyses. As stated previously in the 35 USC 102 rejection, Rine et al. disclose using various physical matrices including microarray data and value sets (i.e. col. 2, 5, and 10). Applicants argue that Rine et al. (col. 2, lines 30-44) fail to describe the inclusion of two or more different types of data into a value set that represent the various interactions, relationships, and dependencies of the system components. This statement

is found confusing as the instant claims do not recite such a limitation. For example, instant claim 1 (line 7) merely recites "two or more different types of data elements". Applicants argue Rine et al. do not describe any data elements measured from the physical matrix of responders that are associated into values and integrated into an integration map, as claimed. This statement is found unpersuasive as the limitations of being integrated into an integration map is not found in the instant claims. Applicants arguments are deemed unpersuasive for the reasons set forth above.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The

faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (571) 272-0811.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tiffany Tabb whose telephone number is (571) 272-0556.

MARJORIE A. MORAN
PRIMARY EXAMINER
Marjorie A. Moran
8/3/06

July 24, 2006